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REC'D 22 MAY 2003

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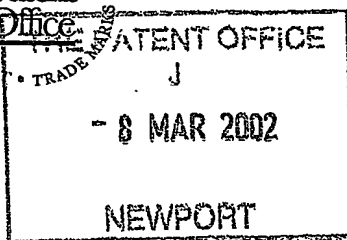
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Signed

W. Evans

Dated

17 April 2003



Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

0200070

2. Patent application number

(The Patent Office will fill in this part)

0205447.6

08MAR02 E701788-1 C260408 MAR 2002
P01/7700 0.00-0205447.6

3. Full name, address and postcode of the or of each applicant (underline all surnames)

SMITHS GROUP PLC
765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

8032310001 ✓

GB

4. Title of the invention

MASK APPARATUS

5. Name of your agent (if you have one)

J. M. FLINT

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number (if you know it)

1063304001 ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

YES

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d))

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description 5

Claim(s)

Abstract

Drawing(s) 2 to 2

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date 7 March 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

J.M. FLINT 020 8457 8220

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MASK APPARATUS

This invention relates to mask apparatus.

Masks are used to supply air or other gas to a patient via his mouth, nose or both. Masks take many different forms but the most common comprises a semi-rigid domed shell shaped to fit around the periphery of both the nose and mouth. The shell usually has some form of softer material around its edge, which provides a seal with the skin surface. An opening in the mask includes a coupling by which the mask is connected to ventilation or anaesthesia equipment. The shell is usually retained in position by means of straps extending around the rear of the patient's head and adjustably fastened to opposite sides of the shell.

There are various problems with existing masks. One problem is that of achieving an effective seal with the contours of the face. Although it is not essential to provide a completely gas-tight seal with the skin surface, if there is not a good fit, gas escaping between the mask and skin can cause discomfort to the patient. Attempts to increase the seal by tightening the straps can increase pressure on the face, which also causes discomfort. Another problem with masks that enclose the nose is that some patients find them claustrophobic. Also, they often prevent the patient wearing spectacles. The straps used to hold the mask on the head can often be difficult to position and adjust correctly. If the mask has to be removed repeatedly to enable access to the patient's mouth it can be time-consuming to have to readjust and reposition the straps of the mask each time it is removed and replaced.

One important use of breathing masks is in CPAP (continuous positive airway pressure) or BIPAP (bi-directional positive airway pressure) ventilation for relieving sleep apnoea by keeping the airways free and open when the muscles of the respiratory tract relax during sleep. In sleep apnoea applications the mask is often worn at home. It is particularly important for such masks to be easy to use and comfortable. Where masks are used in hospitals this is often in intensive care units for patients with heart failure, pulmonary disease or other respiratory problems. CPAP is used to inflate the lungs to a higher functional capacity to allow easier and more effective oxygen transfer.

It is an object of the present invention to provide an alternative mask apparatus.

According to one aspect of the present invention there is provided mask apparatus including a generally ring-shape sealing assembly adapted to seal around at least the mouth of a user and having a central opening located in the region of the mouth, harness means attached with the sealing assembly and arranged to extend around the head of the user to retain the sealing assembly in position, and closure means for removably securing with the central opening, the closure means including gas inlet means.

Other aspects of the invention will become apparent from the following, which is a description of mask apparatus according to the present invention, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side elevation view of the mask;

Figure 2 is a partly cut-away side elevation view of the mask;

Figure 3 is a perspective view illustrating removal of the closure means;
and

Figure 4 is a perspective view from the rear and above of the sealing
assembly.

The mask has a sealing assembly or collar 1 of a semi-rigid, impervious foamed plastics material. The collar 1 is of ring shape with a central rectangular opening 2 located in front of the user's mouth. At its upper end, the assembly 1 has a shallow part-circular wall 3 extending around a horizontal shelf 4, which forms the floor of a recess 5 in the upper end of the mask. The shelf 4 has a laterally-extending slot 6 through it positioned to align with the nostrils of the user. The recess 5 contains a wedge-shape insert 7 of a gel material, which also has a lateral slot 8 that aligns with the slot 6 in the shelf 4 so as to provide a gas passage to the nostrils. The gel insert 7 seals around the nostrils of the user to confine gas flow through the slots 6 and 8 to the nasal passages. The peripheral edge 9 of the collar 1 extends under the chin, up opposite sides of the mouth and across the top of the mouth between the mouth and the nose. The nature of the material of the collar 1 is such that its edge 9 conforms to the contours of the face to form an effective seal.

The collar 1 is attached with a harness 20 by which the mask is secured to the user's head. The harness 20 is in two halves 21 that extend around the left and right sides of the user's head and that are secured together at the back of the head by engaging cooperating

hook and loop fabric fasteners 22. Each half 21 of the harness 20 is formed of a single piece of flexible, breathable, elastic material of generally triangular shape with three limbs 23, 24 and 25 and a open centre 26. The forward end 27 of each half 21 of the harness is attached with opposite sides of the collar 1. Two of the limbs 23 and 24 extend rearwardly from the end 27 below and above the user's ear, which is accommodated in the open centre 26. The third limb 25 extends substantially vertically along the back of the head, joining the rear ends of the limbs 23 and 24. The third limb 25 on each half 21 of the harness supports the hook and loop fasteners 22 so that these limbs can be joined with one another at the rear of the head.

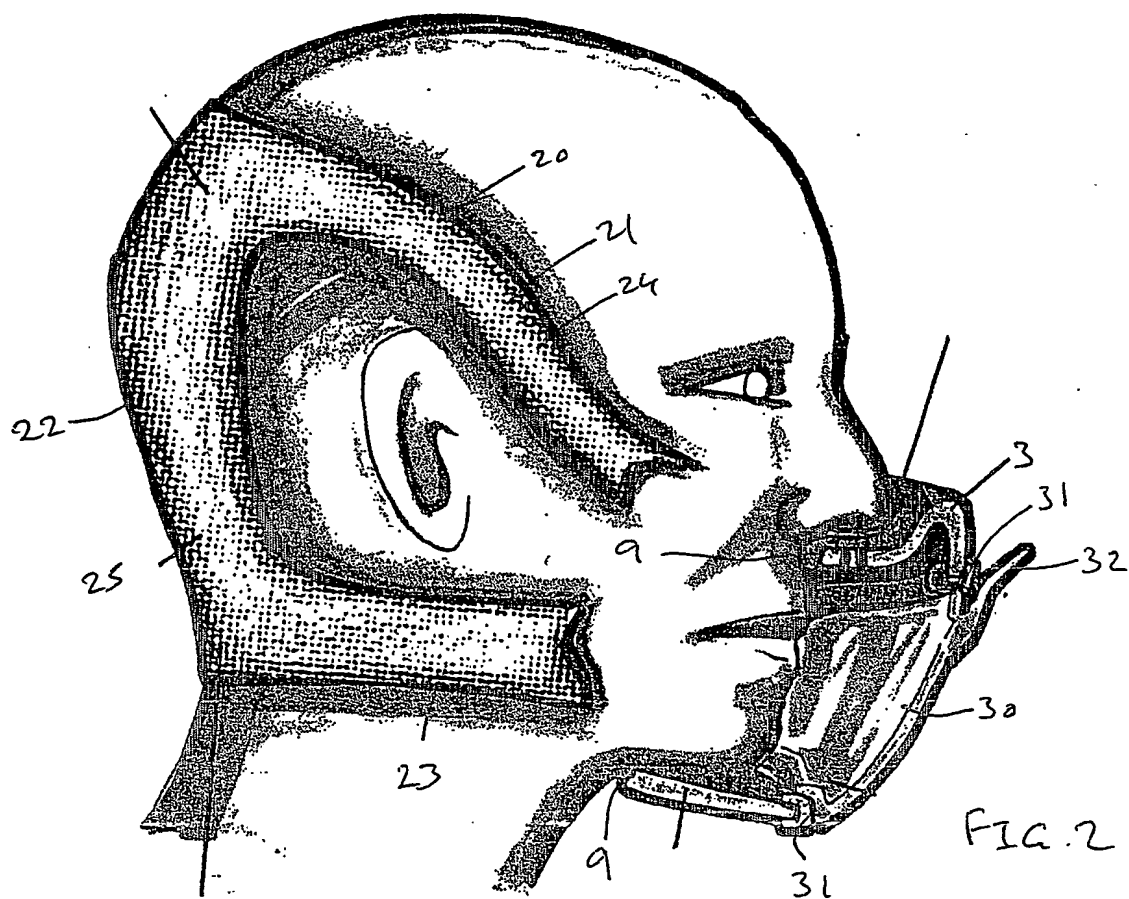
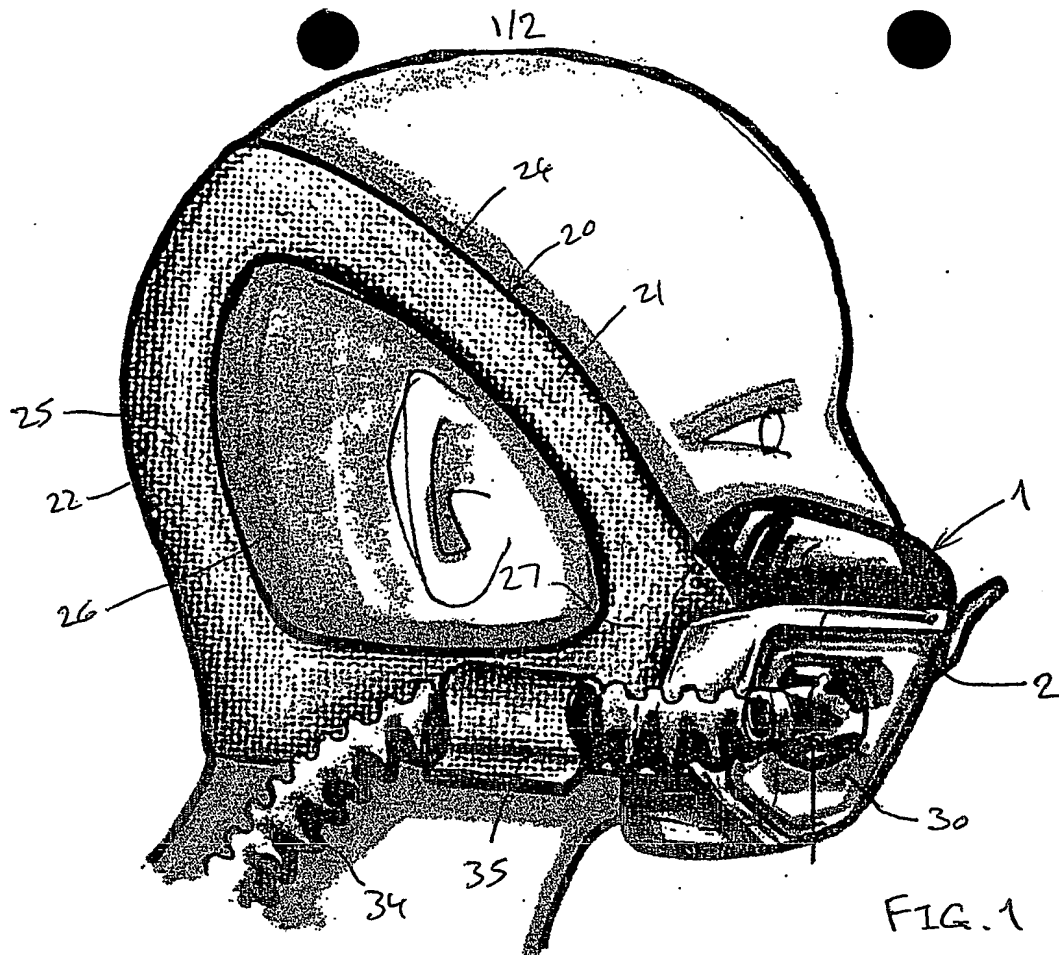
The mask assembly is completed by a cover plate or window 30 fitted in the central opening 2 of the collar 1. The window 30 is of a rigid but bendable transparent plastics material. It is generally rectangular in shape being curved substantially in a semi-circle across its width and being flat or slightly convex in a vertical direction when viewed externally of the mask. The edge 31 of the window is shaped so that it is a push or click fit in the opening 2 of the collar 1, which is of a softer material. A catch tongue 32 projects forwardly and upwardly from the centre of the upper edge of the window. Towards one side of the window 30 there is a gas inlet port 33 connected with gas tubing 34, which extends along the side of the head and is supported by a tab fastener 35 on the harness.

In use, the sealing collar 1 is first positioned over the mouth with the nose received in the recess. The two halves 21 of the harness 20 are then passed around the side of the head and secured together at the back of the head. In this state, the user is able to breathe through both his mouth and nose via the central opening 2 in the collar 1. When the patient needs

ventilation, the window 30 with the tubing 34 attached is clipped into the opening 2. The tubing 34 is then secured with the harness 20 by means of the tab fastener 35. The transparent nature of the window 30 enables the mouth area of the patient to be viewed readily.

If access is needed to the mouth area this can be obtained by removing the window 30 simply by gripping and pulling on the catch 32. This avoids the need to remove the mask in its entirety, which is a particular advantage where a gel, adhesive or similar material is used to provide the seal or a part of the seal. The window 30 can be readily removed and replaced by the user himself where ventilation is only required intermittently.

The seal of the collar with the patient's skin can be improved by means of an adhesive or gel strip extending around the edge of the collar.



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